

1 STAPEDIAL PROSTHESIS AND METHOD OF IMPLANTING THE SAME

2  
3 BACKGROUND

4  
5 1. Field of Invention

6 The present invention relates to ossicular prostheses,  
7 more particularly to an improved stapedial prosthesis.

8  
9 2. State Of The Art

10 *Medical Background: Stapes Diseases*

11 Referring to prior art Figs. 1 and 2, in a normal ear,  
12 sound energy, which consists of vibrations of air molecules, is  
13 directed by the auricle, or outer ear, through the ear canal to  
14 the tympanic membrane. Movements of the tympanic membrane are  
15 transferred to the ossicles, or the ossicular chain of the bones  
16 of the middle ear: malleus, incus and stapes. These movements  
17 eventually reach the inner ear labyrinth fluids via the stapes,  
18 which rests in a small groove, commonly called the oval window.  
19 The oval window is in intimate contact with the inner ear  
20 fluids. The movement of the inner ear fluids then stimulates  
21 the fine sensory organs of the inner ear, which in turn

1 stimulate the auditory nerve, finally transferring the original  
2 sound energy to the brain.

3  
4 Certain pathologies within the middle ear ossicular chain  
5 interrupt the transmission of sound energy and cause hearing  
6 loss. When this occurs, re-construction of the ossicular chain,  
7 using man-made prostheses, is often required. Three general  
8 conditions of discontinuity exist in which a prosthesis is  
9 appropriate. When the malleus, incus and stapes are absent, a  
10 Total Ossicular Replacement Prosthesis (or TORP) is used. When  
11 the stapes is absent but the malleus and incus are present, a  
12 Partial Ossicular Replacement Prosthesis (or PORP) is used. When  
13 the stapes footplate is fixed due to a condition referred to as  
14 otosclerosis, a stapes prosthesis is used.

15  
16 Otosclerosis is one of the most common causes of  
17 progressive hearing loss in which there is an abnormal growth of  
18 bone in the ear. When otosclerosis is present there is an  
19 abnormal, microscopic growth of bone in the walls of the middle  
20 ear. This abnormal growth impedes the conduction of sound energy  
21 from the tympanic membrane to the inner ear. In particular,

1 otosclerosis affects the stapes bone by causing it to become  
2 frozen in place or "fixed." Normally the stapes vibrates freely  
3 to allow the transmission of sound energy into the inner ear.  
4 When it becomes fixed to the surrounding bone, it prevents sound  
5 waves from reaching the inner ear fluids, and thus hearing is  
6 impaired.

7  
8 When the amount of otosclerosis at this location is  
9 significant, as determined by careful hearing tests, surgery has  
10 been found to be the most effective method of improving hearing  
11 loss caused by this condition. This surgery is termed a  
12 stapedectomy and serves to restore continuity between the incus  
13 and inner ear fluids. A stapedectomy is sometimes performed in  
14 patients who have a congenital abnormality of the stapes or have  
15 sustained a fracture of the stapes from traumatic incident.  
16 However, the most common indication for a stapedectomy is  
17 otosclerosis.

#### 18 *Medical Background: Stapedectomy Surgery Technique*

19 Surgical treatment for otosclerosis has been available for  
20 about 45 years. The first operation for this disease was the  
21

1 fenestration procedure, which required mastoid surgery and an  
2 artificial opening in another part of the inner ear. The  
3 attention of surgeons became focused on the diseased stapes  
4 itself and the stapes mobilization procedure was developed.  
5 With the improvement in surgical techniques, the treatment of  
6 choice became stapedectomy. This procedure was first performed  
7 in 1956 and has remained the mainstay of treatment for  
8 otosclerosis.

9  
10 The objectives of stapedectomy are: (1) to open the oval  
11 window for sound entry into the inner ear labyrinth; (2) to  
12 reconstruct a conductive bridge between the incus and the  
13 labyrinth; and (3) to accomplish these goals as efficiently and  
14 physiologically compatible as possible for long-term hearing  
15 without complication. To accomplish these objectives the  
16 stapedectomy is performed through an incision in the ear canal  
17 under local or general anesthesia. A flap consisting of canal  
18 skin and tympanic membrane is elevated and the posterior  
19 superior bony external auditory canal wall is removed, usually  
20 by a drill, to expose the malleus, incus, stapes and chorda  
21 tympani (facial nerve). The ossicles are inspected and palpated

1 to establish the precise diagnosis of the conductive hearing  
2 loss; that is, the fixation of the stapes and mobility of the  
3 malleus and incus are confirmed. The distance between the  
4 undersurface of the incus and the stapes footplate is then  
5 measured to determine the prosthesis length.

6  
7 With care taken to preserve the chorda tympani, the  
8 synovial joint between the lenticular process of the incus and  
9 the head of the stapes is separated (incudostapedial joint). The  
10 stapes tendon and one crus (leg) of the stapes is then severed.  
11 The arch of the stapes may then be removed by fracturing the  
12 other crus while allowing the stapes footplate to remain in the  
13 oval window. An opening is created in the footplate to allow  
14 entrance for a stapedial prosthesis. In some cases, the  
15 footplate is removed and a vein is grafted to the internal wall  
16 of the tympanum to cover the opening and to support the stapes  
17 prosthesis. After the opening is made in the footplate, or  
18 tissue is placed over the opening made to the inner ear after  
19 removing the footplate, one end of a stapedial prosthesis of  
20 proper length is posted in the opening while the other end is  
21 attached to the incus. The incus is gently palpated to observe

1 the motion of the stapedial prosthesis. A piece of fat or tissue  
2 is applied (obtained, as one example, from a small incision  
3 behind the ear lobe) in order to seal any hole in the oval  
4 window. Finally, the eardrum is folded back into its normal  
5 position.

6  
7 *Medical Background: Prior Art Prostheses*

8 A critical part of the stapedectomy procedure is attaching  
9 the prosthesis around the lenticular process of the incus due to  
10 its miniature size, typically about 3.5 mm to 6 mm long and 0.4  
11 mm to 0.8 mm diameter, and its delicate nature. There have been  
12 several devices proposed for the stapedial prosthesis. One  
13 class includes those that use a crimping technique. For  
14 instance, in U.S. Pat. No. 5,370,689 to Causse, one end of the  
15 prosthesis, fabricated of PTFE, is posted in an opening drilled  
16 in the exposed footplate, and a split eyelet at the other end  
17 must be crimped around the incus. In U.S. Pat. No. 3,711,869 to  
18 Shea Jr. one end of the prosthesis is placed on a vein graft  
19 invaginated into the oval window, and a split eyelet at the  
20 other end must be forced open by elastic deformation to fit onto  
21 the incus. Elastic recovery capacity of the eyelet causes it to

1 restore to its original form in about 20 minutes and grip the  
2 incus firmly. U.S. Pat. No. 3,838,468 to Armstrong discloses a  
3 stapedial prosthesis for use in cases where the footplate is  
4 also removed. A piston is fixed at one end to a vein graft for  
5 covering the oval window. A wire of stainless steel, platinum,  
6 gold, or like biocompatible material shaped like a shepherd's  
7 crook extending from the other end, is crimped about the  
8 lenticular process of the incus.

9  
10 Another type of prosthesis in use is the "bucket-handle  
11 prosthesis," which in comparison to the traditional crimped  
12 stapes prosthesis discussed above, is reportedly easier to  
13 insert (as discussed by Rothbaum, et. al in "Task performance in  
14 stapledotomy: Comparison between surgeons of different experience  
15 levels, " *Otolaryngol Head Neck Surg.* 128:71-7 (2003)).

16 Referring to prior art Figs. 3 and 4, U.S. Pat. No. 3,196,462 to  
17 Robinson discloses one type of bucket-handle device 10, also  
18 termed the bucket-and-bail device, which includes a bucket 12  
19 (also termed a well or a socket), a wire bail 14 (handle) at one  
20 end for receiving and securing a portion of the disarticulated  
21 lenticular process 16 of the incus 18, and a cylindrical shaft

1 portion 20 (or stem or rod) at the other end for engaging the  
2 oval window 22, or tissue 24 (e.g., a vein graft or fat tissue)  
3 that is placed over the opening made to the inner ear after  
4 removing the footplate. The bail 14 is oriented by the surgeon  
5 so that its axis of pivotal rotation generally is horizontal.  
6 With the prosthesis 10 in that configuration, the incus  
7 lenticular process 16 is positioned in the bucket 12 and the  
8 bail 14 is rotated in an upward arc about a fulcrum point on the  
9 bucket, past the horizontal, until the bail contacts the long  
10 process of the incus 18. In this particular device, only the  
11 frictional engagement of the bail 14 against the incus 18 holds  
12 the bail in place. If the bail should rotate downwardly, out of  
13 range of contact with the incus, the prosthesis may become  
14 dislodged and extrusion may result. In contrast, with a  
15 crimpable wire-crook prosthesis, a short term risk is that the  
16 prosthesis will fracture the incus. Additionally, a loose  
17 fitting crimpable prosthesis may erode or wear away the incus  
18 from irregular loose vibration. Thus, the challenge of  
19 stapedial prostheses, whether a bucket-and-bail type or a  
20 crimpable type is to secure the prosthesis sufficiently well to  
21 the incus to avoid its failing out of position while being



1 careful not to have a connection to the incus that allows the  
2 incus to erode or to fracture.

3  
4 U.S. Patent No. 4,292,693 to Shea et. al discloses one  
5 means for overcoming the bail securement problem. Referring to  
6 prior art Figs. 5 and 6, the stapedial prosthesis 40 of Shea et  
7 al. provides a pair of cam surfaces 42 oppositely mounted on the  
8 bucket portion 44 which permits overcenter pivotal movement of  
9 the bail 46 in one direction and thereafter prevents overcenter  
10 pivotal movement of the bail in the opposite direction. Each of  
11 the cam surfaces 42 tapers outwardly from the surface of the  
12 bucket portion 44 in the direction the overcenter pivotal  
13 movement of the bail 46 is permitted, and terminates in an  
14 inwardly extending shoulder portion 48 which engages the bail 46  
15 to prevent the overcenter pivotal movement thereof in the  
16 opposite direction.

17  
18 Currently, these bail handles are constructed from  
19 stainless steel. Current attachment methods of the bail handle  
20 to the bucket in bail-and-bucket device require that the bucket  
21 handle protrude into the bucket of the prosthesis, thus

1 disturbing the incus process as it lies in the bucket, which  
2 further creates problems in measuring the prosthesis bucket for  
3 a correct fit. During the manufacturing process, a through-hole  
4 50 is first made completely through the bucket body 44. The  
5 bail 46 is then formed into a generally elongated D-shaped  
6 configuration with ends turned inwardly at right angles. The  
7 bail 46 is preferably formed of a single strand of stainless  
8 steel wire with its ends 52, 54 joined in abutting relationship  
9 as by a weld 56, twisting or crimping. The stainless steel  
10 material of the bail 46 is such that one end may be deformed and  
11 inserted completely through the hole 50 so that the weld 56 may  
12 be made. Thereafter, the weld 56 is pulled into the through-  
13 hole 50 until it is approximately centered and the deformed  
14 portion resumes its original shape. This securement method  
15 results in a variability of size and maneuverability in the bail  
16 handle, which further complicates the surgical insertion of the  
17 device.

18  
19 It is readily apparent that great care and skill are  
20 required to secure these and similar prostheses to the  
21 lenticular process of the incus. The minute size of the

1 prostheses also makes them extremely difficult to manipulate  
2 into proper position for tightening around the incus, even with  
3 state-of-the-art microsurgical instrumentation. This is made  
4 more difficult as during the stapedectomy surgery, the view at  
5 the prosthesis insertion site is restricted.

6  
7 As mentioned above, measurement and selection of the  
8 prosthesis, which is affected by current manufacturing  
9 processes, is critical for proper functionality. Once in place,  
10 if the prosthesis is not tightened sufficiently about the incus,  
11 fluctuating hearing loss, dizziness, or extrusion of the  
12 prosthesis may occur. If it is too tight, necrosis of the incus  
13 may occur. In either case, the securement method in itself may  
14 cause trauma to the delicate middle ear structures, including  
15 fracture or subluxation (dislocation) of the incus.

16  
17 Therefore, from the above, it can be appreciated that there  
18 is a need for an improved bucket-handle prosthesis, particularly  
19 with respect to manufacturing repeatability of the bail handle  
20 and easier and more proficient attachment to the incus process.

## SUMMARY OF THE INVENTION

It is therefore an object of the invention to provide an improved bucket-handle stapedial prosthesis.

It is another object of the invention to provide a stapedial prosthesis which facilitates manufacture, assembly and surgical implantation.

It is also an object of the invention to provide a visual cue for the surgeon that aids in depth perception while operating in the middle ear area.

It is an additional object of the invention to provide a stapedial prosthesis that better conforms to a patient's anatomy.

It is a further object of the invention to provide a stapedial prosthesis that is adaptable in size for the incus.

1       It is yet another object of the invention to provide a  
2   stapedial prosthesis that provides better transmission of sound  
3   energy, and thus better hearing results.

4  
5       It is yet an additional object of the invention to provide  
6   a stapedial prosthesis that does not cause artifacts on MRI  
7   images.

8  
9       In accord with these objects, a stapedial prosthesis is  
10   provided and includes a bucket body, a bail handle, and a  
11   shaft. In accord with one preferred aspect of the invention,  
12   the bucket body preferably includes a plurality of slots  
13   positioned in the bucket wall which allow selected segments of  
14   the bucket wall to bend inwardly or outwardly. When these wall  
15   segments are manipulated by the surgeon, the bucket can adapt  
16   to a variety of incus process diameters.

17  
18       In accord with a second preferred aspect of the invention,  
19   the prosthesis overcomes certain problems in the prior art by  
20   constructing the bail handle from a resilient material, such as  
21   titanium. By using the spring-like tension of titanium, the

1 bail handle is secured in two holes within the wall of bucket  
2 body in such a way that allows complete freedom and  
3 unobstruction to the incus process as it lies in the bucket.  
4 The spring tension of the bail handle causes the handle to  
5 remain affixed to the bucket without welding, twisting or  
6 crimping, and the handle does not extend all the way through the  
7 body as in prior art devices. Since there is no welding,  
8 twisting or crimping, there is a more uniform fit and movement  
9 of the bail handle when attached to the bucket, thus aiding  
10 further in the installation of the prosthesis. Furthermore, the  
11 handle, once manipulated by the surgeon, remains in a fixed  
12 relation relative to the bucket. Additionally, the use of  
13 titanium provides less imaging artifact in magnetic resonance  
14 imaging situations as titanium is a more MRI transparent  
15 material than stainless steel.

16  
17 In accord with a third preferred aspect of the invention,  
18 visualization of the prosthesis during implantation is aided by  
19 providing a shaft portion of the device with a central portion  
20 having a relative smaller diameter than a distal end portion  
21 which attaches to or adjacent the anatomical oval window. This

1 change in dimension provides a visual cue for the surgeon as the  
2 surgeon places the prosthesis into the opening made in the oval  
3 window. The smaller diameter central portion of the shaft also  
4 helps to reduce the mass of the device thus aiding in the sound  
5 energy transmission from the tympanic membrane to the inner ear.  
6

7 Additional objects and advantages of the invention will  
8 become apparent to those skilled in the art upon reference to  
9 the detailed description taken in conjunction with the provided  
10 figures.  
11

#### 12 BRIEF DESCRIPTION OF THE DRAWINGS

13

14 Prior art Fig. 1 is a cross-sectional profile of the human  
15 ear;  
16

17 Prior art Fig. 2 is a cross-sectional profile of the human  
18 ear showing the ossicular chain;  
19

20 Prior art Fig. 3 is a perspective view of a prior art  
21 bucket-handle stapedial prosthesis;

1

2       Prior art Fig. 4 is a side elevation view of the prior art  
3       stapedial prosthesis of Fig. 3, shown implanted between the  
4       incus and the oval window;

5

6       Prior art Fig. 5 is a perspective view of another prior art  
7       bucket-handle stapedial prosthesis;

8

9       Prior art Fig. 6 is a cross-sectional profile of the prior  
10      art stapedial prosthesis of Fig. 5, showing the weld joint of  
11      the wire bail;

12

13      Fig. 7 is an exploded view of a bucket-handle stapedial  
14      prosthesis according to the present invention;

15

16      Fig. 8 is a front elevation view of the stapedial  
17      prosthesis of Fig. 7;

18

19      Fig. 9 is a rear elevation of the stapedial prosthesis of  
20      Fig. 7;

21



1        Fig. 10 is a right side elevation view of the stapedial  
2 prosthesis of Fig. 7;

3  
4        Fig. 11 is a perspective view of a first portion of the  
5 stapedial prosthesis implantation procedure; and

6  
7        Fig. 12 is a perspective view of a second portion of the  
8 stapedial prosthesis implantation procedure.

9  
10            DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

11        Referring to Figs. 7 through 10, a preferred embodiment of  
12 a stapedial prosthesis 100 includes a body 102 and a bail  
13 handle 104. The body 102 is preferably constructed from  
14 commercially pure Grade 2 titanium, and is further defined by a  
15 closed-bottom bowl shaped cavity, termed the bucket 106 (or  
16 well), which tapers down to a shaft 108 (also termed a stem or  
17 a rod). The bucket 106 of the body 102 is sized to accept the  
18 long process and lenticular process of the incus. The body 102  
19 of the prosthesis 100 preferably defines four holes 110, 112,  
20 114, 116, each designed for a specific purpose as now  
21 described. The two diametrically-opposed holes 110, 112 near

1 the bottom of the bucket 106 are receptacles (bail insert  
2 openings) for receiving ends 118, 120 of the bail handle 104,  
3 described below. The hole 114 located at the rear of the  
4 bucket 106 near the rim 142 is intended for positioning the  
5 prosthesis 100. That is, a surgeon can insert a pick 200 and  
6 turn the prosthesis 100 to achieve an optimum fit for each  
7 patient, as described in more detail below with respect to Fig.  
8 11. The hole 116 near the distal end of the shaft 108 is  
9 optional, and where provided allows for tissue in-growth and  
10 further stabilization of the device, as the distal end of the  
11 shaft end engages the oval window, or graft tissue that is  
12 placed over the fenestration made to the inner ear after  
13 removing the anatomical footplate, as described in detail  
14 below.

15  
16 According to one preferred aspect of the prosthesis 100,  
17 the diameter of the bucket 106 is adjustable. A preferred  
18 mechanism for adjusting the diameter includes a plurality of  
19 slots 128 provided in the wall 130 of the bucket 106 (four  
20 slots being shown, although more or fewer could be used) which  
21 define individual wall segments 132 (Fig. 10). Each slot 128

1 is preferably about 0.1-mm wide, and defines an arc about the  
2 circumference of the bucket 106 which is substantially smaller  
3 than that traversed by each wall segment 132, e.g., by a factor  
4 of four or more. The slots 128 permit the segments 132 of the  
5 bucket wall 130 to be bent inwardly or outwardly. When the  
6 wall segments 132 are manipulated by the surgeon, the bucket  
7 can adapt to a variety of incus process diameters. Note that  
8 the slots 128 preferably extend down the side of the bucket 106  
9 until just above the bail insert openings 110, 112, thus not  
10 affecting the bail-to-bucket connection, described below.

11  
12 The bucket 106 optionally has an incus notch 140 in the  
13 rim 142 of the bucket wall 130. A prosthesis with an incus  
14 notch 140 in the bucket 106 is generally selected by the  
15 surgeon when a determination is made that the incus is too  
16 eroded or too short for a closed (non-notched) bucket. As  
17 such, alternatively, a closed bucket can be provided to the  
18 prosthesis for use with an incus having good form. In such an  
19 embodiment, the front and rear views of the bucket 106 would  
20 generally be as shown in Fig. 9, with manipulation hole 114  
21 optionally not being provided at the front of the bucket.

1        According to another preferred aspect of the prosthesis  
2 100, the bail handle 104 is a generally U-shaped or smoothly-  
3 arced structure. In addition, the handle is preferably  
4 constructed from titanium, and more preferably 0.125-mm (0.005")  
5 diameter commercially-pure Grade 4 titanium. The handle 104 has  
6 end portions 118, 120 which are inwardly directed toward each  
7 other and define a space therebetween that is smaller than the  
8 outer diameter of the bucket 106 at the bail insert openings  
9 110, 112.

10  
11        The handle 104 is designed to be freely manipulated by the  
12 surgeon relative to the bucket 106 (rotating about the openings  
13 110, 112) so that it can be flipped up and over the incus once  
14 the incus lenticular process has been placed in the bucket 106  
15 of the prosthesis 100. The handle 104 acts as a means for  
16 stabilizing the prosthesis relative to the incus process by  
17 holding the incus in place, and further prevents the prosthesis  
18 from slipping off of the incus. The properties of titanium, as  
19 the preferred material for the handle, contribute in several  
20 areas with respect to the prosthesis 100. Since titanium has  
21 better spring-like mechanical properties than stainless steel,

1 this characteristic can be used to hold the handle 104 to the  
2 bucket 106 of the prosthesis, e.g., the spring-like tension  
3 forces the ends 118, 120 of the handle 104 into the bail insert  
4 openings 110, 112, thus holding the handle 104 to the bucket 106  
5 without the need for welding, twisting or crimping. The ends  
6 118, 120 of the bail handle 104 are not coupled to each other,  
7 do not contact each other, and do not pass each other within the  
8 bucket 106. And once manipulated by the surgeon, the bail  
9 handle 104 under tension remains in a fixed relationship  
10 relative to the bucket 106 without concern of unintended  
11 movement which may otherwise result in undesirable loosening of  
12 the incus relative to the prosthesis 100.

13  
14 With respect to manufacturing and assembly advantages,  
15 because the handle 104 is formed prior to assembly, and  
16 considering the handle material is preferably titanium, the  
17 handle has a relatively low mass and presents a more uniform,  
18 repeatable shape. During the assembly process, the ends 118,  
19 120 of the handle 104 are slightly spread apart, manipulated  
20 about the bucket 106 and then released into the bail insert  
21 openings 110, 112 of the bucket 106 of the prosthesis, a much

1 simpler method than current approaches. Due to this simplified  
2 assembly technique, manufactured units are more uniform.  
3 Furthermore, the bail handle 104 does not protrude into the  
4 bucket 106, and thus the cavity of the bucket 106 remains open  
5 permitting a more complete fit of the incus process within the  
6 bucket.

7  
8 Referring specifically to Fig. 7, according to another  
9 preferred aspect of the prosthesis, the shaft 108 of the  
10 stapedial prosthesis 100 has a central section 160 and a distal  
11 section 162 of different diameters. The bucket 106 tapers down  
12 to the central section 160 of the shaft 108 to a diameter of  
13 approximately 0.3-mm. The shaft 108 continues at this diameter  
14 until reaching the distal section 162 where it enlarges in  
15 diameter, preferably to approximately 0.4-mm to 0.8-mm. This  
16 varying diameter provides at least two advantages. First, the  
17 mass of the prosthesis 100 is reduced, which in turn aids in the  
18 conduction of sound, and thus the patient's hearing. Second, a  
19 visual cue is provided to the surgeon of the location of the  
20 distal section 162 of the prosthesis within the middle ear area.

1 Referring now to Figs. 11 and 12, the implantation of the  
2 prosthesis 100 will now be described, wherein the prosthesis is  
3 provided with the incus notch 140. Implantation using a closed  
4 bucket (non-notched) design proceeds in a similar manner.

5  
6 Referring specifically to Fig. 11, after the surgeon  
7 removes the stapes and performs the necessary steps preparatory  
8 to implantation of the stapedial prosthesis of the present  
9 invention, e.g., creating a stapedotomy opening in the footplate  
10 to allow entrance for the stapedial prosthesis, or covering the  
11 oval window 22 with a tissue graft 24 of the surgeon's choice,  
12 the prosthesis 100 is inserted into position using forceps. In  
13 so doing, the distal section 162 of the prosthesis is placed  
14 against the graft tissue 24. The prosthesis can be manipulated  
15 into a desired orientation by engaging the upper opening 114 of  
16 the prosthesis 100 with a right angle pick tool 200 and  
17 manipulating the prosthesis therewith. In proper orientation,  
18 the incus notch 140 will be located at the top of the lenticular  
19 process 16 of the incus 18, with a portion of the lenticular  
20 process inserted into the incus notch 140 of the bucket 106.  
21 During the initial step of the insertion procedure, the bail

1 handle 104 is rotated to the side of the bucket 106 having the  
2 upper opening 114 for the positioning tool (i.e., opposite the  
3 notch 140). The surgeon then gently moves the incus process (in  
4 the direction of arrow 202), rotates the prosthesis (in the  
5 direction of arrow 204), and sets the lenticular process 16 into  
6 the bucket 106.

7  
8 Where the bucket wall 130 is segmented, the surgeon has two  
9 options for adapting the size of the bucket 106 to the size of  
10 the incus process 16. In a first approach, after placing the  
11 incus lenticular process 16 into the bucket 106, the surgeon  
12 bends one or more of the wall segments 132 (Fig. 10) until just  
13 touching the process 16, thus gripping the incus 18. At this  
14 point the surgeon rotates the bail handle 104 to further hold  
15 the incus relative to the prosthesis, preferably as follows.  
16 Referring to Fig. 12, the surgeon rotates and pulls the bail  
17 handle 104 upward and outward so that the bail handle 104 passes  
18 through a plane containing both the bail handle and the  
19 longitudinal axis A of the prosthesis. The surgeon continues  
20 the upward and outward rotation of the bail handle 104 until it  
21 is in proper position about the long process of the incus 18.



1 As the surgeon releases the spring-loaded bail 104, the tension  
2 in the bail handle 104 may aid in holding the incus process 16  
3 within the bucket 106.

4  
5 In a second approach, the surgeon would place the incus  
6 lenticular process 16 into the bucket 106, rotate the bail 104  
7 as described above, then bend one or more wall segments 132  
8 (Fig. 10) until just touching the process, thus gripping the  
9 incus 18 further.

10  
11 As yet another alternative, the wall segments 132 may be  
12 left in their manufactured configuration, and the force of the  
13 bail handle 104 alone is used to hold the incus process 16  
14 relative to the prosthesis 100.

15  
16 With respect to post-operative considerations, the  
17 preferably all-titanium prosthesis has excellent bio-  
18 compatibility and, due to its non-magnetic nature, has little  
19 effect on magnetic resonance imaging (e.g., very low MRI image  
20 artifacts).

1       The device may be constructed in a range of dimensions with  
2   respect to bucket diameters, shaft diameters, and lengths. In  
3   this manner, a device can be selected by the surgeon that  
4   corresponds to the anatomical features of a patient. Exemplar  
5   dimensions follow. The overall length of the body 102 (bucket  
6   106 and shaft 108) is 3.5-mm to 9.0-mm. The bucket 106 has a  
7   length of 0.8-mm to 1.3-mm, a diameter of 0.85-mm to 1.5-mm, and  
8   a wall thickness of 0.1525-mm. One preferred inner diameter of  
9   the bucket 106 is 0.965-mm and one preferred outer diameter of  
10   the bucket is 1.27-mm. Each of the four holes 110, 112, 114,  
11   116 has a diameter of approximately 0.150-mm. The bail handle  
12   104 has a length of 2.13-mm, a width (across parallel shaft  
13   portions 150, 152 of Fig. 7) of 1.49-mm, and a cross-sectional  
14   diameter of 0.125-mm. The shaft 108 has a length of 2.7-mm to  
15   7.7-mm, and a diameter of 0.4-mm to 0.8-mm. Where the shaft has  
16   the preferred varying diameter, the central section 160  
17   preferably has a length of 2.4-mm to 6.7-mm and a diameter of  
18   0.3-mm, and the distal section preferably has a length of 0.3-mm  
19   to 1.0-mm and a diameter of 0.4-mm to 0.8-mm.

20

1        There have been described and illustrated herein  
2        embodiments of a stapedial prosthesis and methods of  
3        implantation of the same. While particular embodiments of the  
4        invention have been described, it is not intended that the  
5        invention be limited thereto, as it is intended that the  
6        invention be as broad in scope as the art will allow and that  
7        the specification be read likewise. Thus, while several  
8        preferred aspects of the invention have been described with  
9        respect to the figures, it is intended that each of the  
10       preferred aspect and other aspects of the invention may be  
11       implemented independently or in combination with one or more  
12       other aspects of the invention. That is, each of the segmented  
13       bucket, the spring-tensioned bail handle, and the shaft with  
14       reduced diameter central portion may be implemented in an  
15       otherwise conventional stapedial prosthesis with or without the  
16       other preferred aspects. In addition, while particular exemplar  
17       dimensions have been disclosed, it is understood that other  
18       dimensions can be provided to the elements of the  
19       prosthesis provided such dimensions allow the prosthesis to be  
20       used as a stapedial prosthesis. Also, while titanium, and more  
21       particularly preferred specific grades of titanium, have been

1 disclosed, it is appreciated that the preferred aspects of the  
2 invention may be implemented in materials other than titanium.  
3 It will therefore be appreciated by those skilled in the art  
4 that yet other modifications could be made to the provided  
5 invention without deviating from its spirit and scope as  
6 claimed.